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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	6

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,633	Applicant(s) ALI ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed August 07, 2003. Upon entering the amendment, the claims 1, 6 and 25 are amended and the claims 11 and13-24 are canceled.

2. The claims 1-10, 12 and 25 are pending and presented for the examination.

Claim Rejections - 35 USC § 112

New matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising an effective amount of a neutralizer designated by the FDA ***as of Feb. 5, 2002***, to neutralize the thickening agent.

The specification as originally filed specifically provides a generic description which supports the neutralizer designated by the FDA(page 8, lines 20-21).

Thus, the limited generic disclosure fails to convey to one of ordinary skill in the art that the inventor had possession of the later claimed subject matter(i.e. a neutralizer designated by the FDA ***as of Feb. 5, 2002***), at the time the application was filed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A FDA guideline is used in a claim as a limitation to identify or describe a particular material or product(i.e. neutralizer), the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. As evidenced by applicant's admission, FDA guideline is not permanent and thus, the claim scope is uncertain.

Since a neutralizer that is generally recognized as safe, designated by the FDA guideline, the standard for safety is not consistent nor permanent. Thus, the FDA guideline cannot be used properly to identify any particular material or product which renders the claims uncertain and indefinite.

Furthermore, the attempt to incorporate subject matter into this application by reference to FDA guideline (Feb. 05, 2002) is improper because essential material may not be incorporated by reference to any publication in any application which is to issue as a US patent, See MPEP § 608.01(p). The claimed subject matter(i.e. neutralizer)

recited in claims 1 and 6 is considered to be "essential material" where it is incorporated by FDA guideline(Feb.5, 2002).

The claims should be particularly and distinctively pointing out the subject matter and every effort made to prevent their use in any manner which might adversely affect their validity.

Thus, due to the reasons set forth above, the claims 1 and 6 are properly included in this rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, 9-10, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Samour et al(US 5,976,566).

The claims are drawn to a composition comprising (a) at least about 60 weight percent of an aliphatic alcohol having C1-C4 such as ethanol or isopropanol; (b) a thickening agent such as carbomer(0.1-5%); and (c) an effective amount of a neutralizer such as sodium hydroxide, wherein the composition is not a mousse and has a density of at least 0.8g/ml.

Samour et al(US'566 hereafter) teach a topical alcoholic gel 55-70% ethanol, isopropanol or mixture thereof, 0-2% of cellulosic thickener, and a base to adjust the

pH, see column 4, lines 30-35. US'566 further teaches incorporation of an appropriate base, such as sodium hydroxide to neutralize the formulation, see column 3, lines 40-49. US'566 also teaches carbopol® acting as a thickening agent, see column 9, lines 1-7.

As to claim 12 that requires a specific viscosity in the range about from 1000 to 65000centipose at 70 Farenheit, the viscosity would have been inherently possessed by the patented composition of US'566 because it would have been conventional knowledge that the viscosity of the topical formulation including gel would be encompassed by the claimed ranges(1000 to 65000centipose). As evidenced by applicant's own admission (in light of the specification, see page 12, lines 9-12, ...gel formulation..), viscosity of the patented gel composition(US'566) would have been naturally embraced by the claimed range.

It is noted that the antimicrobial activity or the density(i.e. at least 0.8g/ml) required by the claims would be possessed inherently by the composition of Mckenzie because all the critical elements are same and the composition is in the form of gel formulation.

All the critical elements required by the claims are taught by the cited reference and thus the claimed subject matter is not considered to be patentably distinct over the prior art of the record.

6. Claims 1-2, 4-7, 9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mckenzie et al(US 5,747,021).

The claims are drawn to a composition comprising (a) at least about 60 weight percent of an aliphatic alcohol having C1-C4 such as isopropanol; (b) a thickening agent such as carbomer(0.1-5%); and (c) an effective amount of a neutralizer such as sodium hydroxide, wherein the composition is not a mousse and has a density of at least 0.8g/ml.

Mckenzie et al(US'021, hereafter) teaches a transparent topical composition comprising isopropyl alcohol, carbomer and sodium hydroxide(0.1%),see column 3, lines 5-14. US'021 also teaches said topical composition is available in the form of gel, lotion, solution, cream, ointment and so on, see claim 6. The effective amount of each component is listed as following: 30-70 weight percent(%) of isopropyl alcohol and 0.25-1.75 weight percent(%) carbomer, claim 7.

As to the claim 12 that requires moisturizers or emollients, US'021 teaches glycerin or PEG-8 for the cosmetic effect(i.e."slip" effect). It is well known to any skilled artisan that said "slip" agent is referring to moisturizer or emollients in the cosmetic field. Thus, one would have readily envisaged the composition of Mckenzie(US'021) met the claim 12, includes moisturizer or emollient.

It is noted that the antimicrobial activity or the density(i.e. at least 0.8g/ml) required by the claims would be possessed inherently by the composition of Mckenzie because all the critical elements are same and the composition is not mousse.

All the critical elements required by the claims are taught by the cited reference and thus the claimed subject matter is not considered to be patentably distinct over the prior art of the record.

7. Claims 1, 4-7, 9 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sequeira et al(US 4,775,529)

The claims are drawn to a composition comprising (a) at least about 60 weight percent of an aliphatic alcohol having C1-C4; (b) a thickening agent such as carbomer(0.1-5%); and (c) an effective amount of a neutralizer such as sodium hydroxide, wherein the composition is not a mousse and has a density of at least 0.8g/ml.

Sequeira et al(US'529, hereafter) teach a topical composition comprising 15-50% by weight propylene glycol, 20-40% by weight isopropyl alcohol, 0.1-3% by weight of a thickening agent(see column 2, lines 60-62), and sodium hydroxide to neuralize the carbomer 940(see column 1, lines 25-30 and column 6, lines 40-49). Since both propylene glycol(C3) and isopropyl alcohol(C3) together make aliphatic alcohol content amount more than 60% by weight, all the claims are anticipated by the teaching of the patented reference(US'529).

It is noted that the antimicrobial activity or the density(i.e. at least 0.8g/ml) required by the claims would be possessed inherently by the composition of US'529 because all the critical elements are same and the composition is not mousse.

All the critical elements required by the claims are taught by the cited reference and thus the claimed subject matter is not considered to be patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al(US 5,976,566) in view of BF Goodrich tech. Disclosure("Neutralizing carbopol....", 1998).

Samour's teaching is mentioned above in 102 rejection(supra).

Applicant's claim differs because it requires a specific neutralizer that contains an amino acid selected from the group consisting arginine, cysteine and thiamine.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to substitute sodium hydroxide with arginine containing neutralizer because BF Goodrich teaches that sodium hydroxide is functionally equivalent to arginine containing neutralizer, see figure 4. Thus, one would have been motivated to do so, with reasonable expectation of success because it is always desirable to have selection option to enhance the efficiency of the manufacturing process and reduce the manufacturing cost due to the convenience to obtain ingredients. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by the cited references.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant

because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614